AMENDED IN ASSEMBLY MAY 30, 2012

AMENDED IN ASSEMBLY MAY 8, 2012

AMENDED IN ASSEMBLY APRIL 25, 2012

AMENDED IN ASSEMBLY MARCH 29, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 2356

Introduced by Assembly Member Skinner

February 24, 2012

An act to amend Section 1644.5 of, and to add Section 1644.6 to, the Health and Safety Code, relating to human tissue.

LEGISLATIVE COUNSEL'S DIGEST

AB 2356, as amended, Skinner. Tissue donation.

Existing law prohibits the transfer of any tissues, as defined, into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), syphilis, and human T lymphotrophic virus (HTLV), except as provided. Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided.

This bill would except sperm donated by a sexually intimate partner of the recipient, as defined, from second or repeat testing under these requirements if the recipient is informed of the testing requirements and signs a written waiver, as specified. This bill would exclude a physician and surgeon from liability for any cause of action ~~or disciplinary action, as specified, for providing insemination or advanced~~

~~reproductive technology services using~~ *based solely upon the use of* sperm from a sexually intimate partner of the recipient when the physician and surgeon *provides insemination or advanced reproductive technology services and* has obtained the informed consent of the recipient, who acknowledges and accepts the risks of using sperm that has not undergone quarantine and repeat testing, as described. *The bill would exclude a physician and surgeon from disciplinary action because the physician and surgeon used sperm in these conditions in providing insemination or advanced reproductive technology services.*

The bill would exclude a physician and surgeon owned and operated clinical laboratory or tissue bank from disciplinary action for providing these insemination or advanced reproductive technology services.

The bill would also ~~exclude~~ *provide that some of its provisions do not create a duty for* a physician and surgeon ~~from liability for a cause of action based upon discrimination against an individual or group if the physician and surgeon refuses to provide insemination or advanced reproductive technology services using~~ *to use* sperm from a sexually intimate partner of the recipient *in providing insemination or advanced reproductive technology services* if the physician and surgeon determines that the insemination or services do not meet specified guidelines for providing insemination or advanced reproductive technology services.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Single women and same-sex female couples using a known donor are unable to access the same fertility services as women seeking to conceive using a male partner.

(b) Women seeking fertility services to help them conceive with a male partner are able to be inseminated using fresh sperm. Because of the practical difficulty of performing the required testing and fears of liability, most fertility services will not provide fresh insemination services to a woman using a donor who is not her partner.

(c) All other women are required to have their donors' sperm frozen, which significantly reduces the chance of conceiving and,

for many donors, means that conception is not possible without much more expensive procedures.

(d) Federal Food and Drug Administration (FDA) regulations require extensive testing, except when the donor is a "sexually intimate partner" (21 C.F.R. 1271.90). This term is not defined in regulations. Based upon the term's ordinary meaning, the term has been construed to apply to heterosexual couples with an ongoing relationship. Because the explicit purpose of the term is to allow donation without testing when the recipient has already been exposed, this term can be interpreted to include women who have already attempted at-home inseminations with their donors' sperm because they have already been exposed through these attempts.

(e) Although California requires testing in all circumstances, the state authorizes waivers of repeat testing for sperm donors known to the recipient.

(f) Until the term ~~sexually intimate partner~~ "*sexually intimate partner"* is explicitly defined by the FDA, it is the intent of the Legislature to provide a clarification that, for the purposes of tissues donated for reproductive use, a "sexually intimate partner" includes any woman who has been exposed to the donor's sperm outside of a medical setting.

(g) It is also the intent of the Legislature to address the potential for confusion amongst treating professionals regarding prevailing regulations and professional guidelines that reference both the term "sexually intimate partner" and the term "known donor." Due to this potential, and in recognition that there are multiple entities that regulate physicians and surgeons and the area of assisted reproductive technologies for which the physician or surgeon is accountable, it is the intent of the Legislature to provide physicians and surgeons with immunity when acting in a manner consistent with this law. ~~Physicians~~ *Both the physician* and surgeons who believe this bill and *the* standard of care allows the use of fresh sperm from a known donor to which the woman has already been exposed constitutes a "sexually intimate partner" and the physician and surgeons who ~~believes~~ *believe that the* use of fresh sperm in this situation is a violation of professional guidelines and ~~declines~~ *decline* to use ~~of~~ fresh sperm ~~both~~ need assurances *that* their actions under this new law ~~should~~ *would* not be subjecting themselves to additional professional risk.

(h) The definition of "sexually intimate partner" is limited to this act and is not intended to have any effect on any provision of the Family Code, including the definition of a "donor" for purposes of determining legal parentage of a child.

(i) It is not the intent of the Legislature to prevent federal regulators from exercising federal authority over facilities that provide insemination or advanced reproductive technology services.

SEC. 2. Section 1644.5 of the Health and Safety Code is amended to read:

1644.5. (a) Except as provided in subdivision (c) or (d), no tissues shall be transferred into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive by laboratory tests for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), and syphilis. For tissues that are rich in viable leukocytes, the tissue shall be tested for evidence of infection with human T lymphotrophic virus (HTLV) and found nonreactive. The department may adopt regulations requiring additional screening tests of donors of tissues when, in the opinion of the department, the action is necessary for the protection of the public, donors, or recipients.

(b) Notwithstanding subdivision (a), infectious disease screening of blood and blood products shall be carried out solely in accordance with Article 2 (commencing with Section 1602.5) of Chapter 4.

(c) All donors of sperm shall be screened and found nonreactive as required under subdivision (a), except in the following instances:

(1) A recipient of sperm, from a sperm donor known to the recipient, may waive a second or other repeat testing of that donor if the recipient is informed of the requirements for testing donors under this section and signs a written waiver.

(2) A recipient of sperm may consent to therapeutic insemination of sperm or use of sperm in other advanced reproductive technologies even if the sperm donor is found reactive for hepatitis B, hepatitis C, syphilis, HIV, or HTLV if the sperm donor is the spouse of, partner of, or designated donor for that recipient. The physician providing insemination or advanced reproductive technology services shall advise the donor and recipient of the potential medical risks associated with receiving sperm from a

reactive donor. The donor and the recipient shall sign a document affirming that each comprehends the potential medical risks of using sperm from a reactive donor for the proposed procedure and that each consents to it. Copies of the document shall be placed in the medical records of the donor and the recipient.

(3) (A) Sperm whose donor has tested reactive for syphilis may be used for the purposes of insemination or advanced reproductive technology only after the donor has been treated for syphilis. Sperm whose donor has tested reactive for hepatitis B may be used for the purposes of insemination or advanced reproductive technology only after the recipient has been vaccinated against hepatitis B.

(B) (i) Sperm whose donor has tested reactive for HIV or HTLV may be used for the purposes of insemination or advanced reproductive technology for a recipient testing negative for HIV or HTLV only after the donor's sperm has been effectively processed to minimize the infectiousness of the sperm for that specific donation and where informed and mutual consent has occurred.

(ii) Not later than January 1, 2014, the department shall adopt regulations regulating facilities that perform sperm processing, pursuant to this subparagraph, that prescribe standards for the handling and storage of sperm samples of carriers of HIV, HTLV, or any other virus as deemed appropriate by the department. The department may propose to adopt, as initial regulations, the recommendations made within the "Guidelines for Reducing Risk of Viral Transmission During Fertility Treatment" as published by the American Society for Reproductive Medicine. Notice of the department's proposed adoption of the regulations shall be posted on the department's Internet Web site for at least 45 days. Public comment shall be accepted by the department for at least 30 days after the conclusion of the 45-day posting period. If a member of the public requests a public hearing during the 30-day comment period, the hearing shall be held prior to the adoption of the regulations. If no member of the public requests a public hearing, the regulations shall be deemed adopted at the conclusion of the 30-day comment period. Comments received shall be considered prior to the adoption of the final initial regulations. The department may modify any guidance published by the American Society for Reproductive Medicine. Adoption of initial regulations by the department pursuant to this subdivision shall not be subject

to the rulemaking requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code and written responses to public comments shall not be required. Updates to the regulations shall be adopted pursuant to the same process. Until the department adopts these regulations, facilities that perform sperm processing pursuant to this section shall follow facility and sperm processing guidelines for the reduction of viral transmission developed by the American Society for Reproductive Medicine. Nothing in this section shall prevent the department from monitoring and inspecting facilities that process sperm to ensure adherence to the regulations, or, until regulations are adopted, to the guidelines set forth by the American Society for Reproductive Medicine.

(iii) Prior to insemination or other advanced reproductive technology services, the physician providing the services shall inform the recipient of sperm from a spouse, partner, or designated donor who has tested reactive for HIV or HTLV of all of the following:

(I) That sperm processing may not eliminate all of the risks of HIV or HTLV transmission.

(II) That the sperm may be tested to determine whether or not it is reactive for HIV or HTLV.

(III) That the recipient must provide documentation to the physician providing insemination or advanced reproductive technology services prior to treatment that she has established an ongoing relationship with another physician to provide for her medical care during and after completion of fertility services.

(IV) The recommendations made within the “Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment” published by the American Society for Reproductive Medicine regarding followup testing for HIV and HTLV after use of sperm from an HIV or HTLV reactive donor and have the recommendations regarding followup testing be documented in the recipient’s medical record.

(iv) The physician providing insemination or advanced reproductive technology services shall also verify, and document in the recipient’s medical record, that the donor of sperm who tests reactive for HIV or HTLV is under the care of a physician managing the HIV or HTLV.

(v) The physician providing insemination or advanced reproductive technology services shall recommend to the physician who will be providing ongoing care to the recipient recommended followup testing for HIV and HTLV according to the "Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment" published by the American Society for Reproductive Medicine, which shall be documented in the recipient's medical record.

(vi) In the event that the recipient becomes HIV or HTLV positive, the physician assuming ongoing care of the recipient shall treat or provide information regarding referral to a physician who can provide ongoing treatment of the HIV or HTLV.

(4) A recipient of sperm donated by a sexually intimate partner of the recipient for reproductive use may waive a second or repeat testing of that donor if the recipient is informed of the donor testing requirements of this section and signs a written waiver. For purposes of this paragraph, "sexually intimate partner of the recipient" includes a known or designated donor to whose sperm the recipient has previously been exposed in a nonmedical setting in an attempt to conceive.

(d) Subdivision (a) shall not apply to the transplantation of tissue from a donor who has not been tested or, with the exception of HIV and HTLV, has been found reactive for the infectious diseases listed in subdivision (a) or for which the department has, by regulation, required additional screening tests, if both of the following conditions are satisfied:

(1) The physician and surgeon performing the transplantation has determined any one or more of the following:

(A) Without the transplantation the intended recipient will most likely die during the period of time necessary to obtain other tissue or to conduct the required tests.

(B) The intended recipient already is diagnosed with the infectious disease for which the donor has tested positive.

(C) The symptoms from the infectious disease for which the donor has tested positive will most likely not appear during the intended recipient's likely lifespan after transplantation with the tissue or may be treated prophylactically if they do appear.

(2) Consent for the use of the tissue has been obtained from the recipient, if possible, or if not possible, from a member of the recipient's family, or the recipient's legal guardian. For purposes

of this section, "family" shall mean spouse, adult son or daughter, either parent, adult brother or sister, or grandparent.

(e) The penalties of Section 1621.5 shall not apply to a sperm donor covered under subdivision (c).

(f) Human breast milk from donors who test reactive for agents of viral hepatitis (HBV and HCV), HTLV, HIV, or syphilis shall not be used for deposit into a milk bank for human ingestion in California.

SEC. 3. Section 1644.6 is added to the Health and Safety Code, to read:

1644.6. (a) ~~A~~ *No* physician and surgeon shall ~~not~~ be subject to liability for damages for any cause of action ~~for providing insemination or advanced reproductive technology services using sperm from~~ *based solely on the use of sperm donated by* a sexually intimate partner of the recipient when the physician and surgeon *provides insemination or advanced reproductive technology services and* has obtained the informed consent of the recipient, who acknowledges and accepts the risks of using sperm that has not undergone quarantine and repeat testing, as described in Section 1644.5.

(b) ~~A~~ *No* physician and surgeon shall ~~not~~ be subject to disciplinary action against his or her professional license, or subject to peer review by a professional association peer review body, as defined in clause (iii) of subparagraph (B) of paragraph (1) of subdivision (a) of Section 805 of the Business and Professions Code, ~~for providing insemination or advanced reproductive technology services using~~ *because the physician and surgeon used* sperm ~~from~~ *donated by* a sexually intimate partner of the recipient *in providing insemination or advanced reproductive technology services* when the physician and surgeon has obtained the informed consent of the recipient who acknowledges and accepts the risks of using sperm that has not undergone quarantine and repeat testing, as described in Section 1644.5.

(c) A clinical laboratory that is owned and operated by a physician and surgeon or a tissue bank that is owned and operated by a physician and surgeon shall not be subject to disciplinary action against its license ~~for~~ *because of the use of sperm donated by a sexually intimate partner of the recipient in* providing insemination or advanced reproductive technology services ~~using sperm from a sexually intimate partner of the recipient~~ when ~~the~~

any physician and surgeon *affiliated with the clinical laboratory or tissue bank* has obtained the informed consent of the recipient, who acknowledges and accepts the risks of using sperm that has not undergone quarantine and repeat testing, as described in Section 1644.5.

(d) ~~A~~ *Nothing in this section shall create a duty for a* physician and surgeon ~~shall not be liable for a cause of action based upon discrimination against an individual or group if the physician and surgeon refuses to provide insemination or advanced reproductive technology services using sperm from a sexually intimate partner of the recipient~~ *to use sperm donated by a sexually intimate partner of the recipient in providing insemination or advanced reproductive technology services* if the physician and surgeon ~~determines~~ *reasonably concludes* that the insemination or services do not meet the 2008 American Society for Reproductive Medicine guidelines for gamete and embryo donation.

(e) Nothing in this section shall be construed to affect any liability that may be imposed pursuant to a federal rule or regulation when a physician and surgeon, clinical laboratory, or tissue bank provides insemination or advanced reproductive technology services.

~~(e)~~

(f) For purposes of this section, "sexually intimate partner" includes a known or designated donor to whose sperm the recipient has previously been exposed in a nonmedical setting in an attempt to conceive.

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